EXHIBIT 92

Dep't of Health & Human Servs., Approval Ltr.: NDA 21-641

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-641

TEVA Pharmaceuticals LTD
Attention: J. Michael Nicholas, Ph.D.
Senior Director, U. S. Regulatory Affairs and Pharmacovigilance
425 Privet Road, P.O. Box 1005
Horsham, PA 19044-8005

Dear Dr. Nicholas:

Please refer to your new drug application (NDA) dated and received September 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azilect (rasagiline mesylate) 0.5mg and 1 mg Tablet

We acknowledge receipt of your submissions dated:

19-Jul-2005	4-Aug-2005	11-Aug-2005	12-Aug-2005
08-Nov-2005	20-Jan-2006	09-Feb-2006	17-Mar-2006
27-Mar-2006			

The March 17, 2006 submission constituted a complete response to our August 4, 2005 action letter.

This new drug application provides for the use of Azilect (rasagiline mesylate) in the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as adjunct therapy to levodopa.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-641**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitments in your submission dated March 17, 2006. These commitments are listed below.

1. A formal tyramine challenge study in the fasted state. This trial will incorporate the following elements:
   - An appropriate number of subjects (e.g. approximately 20 per arm, equal number of males and females 40 to 70 years of age)
   - An appropriate positive control
   - The use of multiple dose levels of rasagiline
   - The use of selegiline as an additional comparator
   - The use of baseline pre-treatment tyramine doses of 25, 50, and 100 mg and dose increments above 100 mg of 100 mg up to 800 mg. Post-treatment tyramine will use a similar dosing as pre-treatment, but starting doses will be lower. Tyramine doses will be administered on separate days
   - The use of blood pressure criterion of three consecutive systolic increases of at least 30 mm Hg with close monitoring at 5 minute intervals over at least 2 hours and collection of at least 3 blood pressure measurements within 15-30 minutes prior to tyramine administration to serve as an integrated average blood pressure for comparison to a threshold pressor response after tyramine
   - Measurement of plasma tyramine at 30 minutes after each tyramine challenge study in all treatment groups.

   Protocol submission Date: July 30, 2006
   Study Start Date: December 30, 2006
   Final Report Submission Date: December 30, 2008

2. To investigate orthostatic blood pressure and pulse timed to rasagiline dosing. This will be evaluated in both the tyramine challenge study listed above and the dose proportionality study listed below (no. 4). The dates of commitments will correspond to the respective dates of the tyramine challenge study and dose proportionality study, respectively.

3. To conduct a thorough QTc study characterizing the effects of rasagiline on cardiac repolarization in humans.

   Protocol submission Date: November 28, 2006
   Study Start Date: February 28, 2007
   Final Report Submission Date: May 31, 2008

4. To investigate the dose-proportionality of daily doses of rasagiline (1, 2 and 6 mg) following multiple-dose administration in healthy young and elderly subjects and the effect of levodopa/carbidopa (single dose) on the pharmacokinetics of rasagiline (multiple dose). A secondary objective of this study will be to evaluate orthostatic blood pressure and pulse rate timed to rasagiline dosing.

   Protocol submission Date: January 20, 2006
   Study Start Date: March 30, 2006
   Final Report Submission Date: February 28, 2007

5. To compare the plasma pharmacokinetic parameters of rasagiline and 1 - aminoindan (1-AI) following once daily repeated dosing of a 1 mg tablet of rasagiline for 8 days in healthy subjects and in subjects with moderate renal impairment.

   Protocol submission Date: January 20, 2006
   Study Start Date: March 30, 2006
   Final Report Submission Date: June 30, 2007

6. To conduct a large, simple, randomized, placebo controlled trial of rasagiline added to standard therapy in approximately 5000 Parkinson's disease patients for a duration of 36 months to assess the relative risk of melanoma.

   Protocol submission Date: January 20, 2006
   Study Start Date: February 28, 2007
   Final Report Submission Date: May 31,201 2 (ongoing review of the data by Data Safety Monitoring Board (DSMB) during the study)

7. To repeat the oral embryo-fetal development study in rabbits. A draft audited report was supplied to Teva by the CRO on March 2, 2006 and is currently under review by Teva.

   Protocol submission Date: January 20, 2006
   Study Start Date: **N/A** (Study completed)
   Final Report Submission Date: October 31, 2006

8 To conduct a comprehensive review of the literature related to dietary tyramine restrictions including information on the tyramine content of various foods and beverages.

   Final Submission Date: November 30, 2006

9 To investigate the effect of levodopa/carbidopa on the pharmacokinetics of rasagiline following multiple-dose administration. This study should also investigate the age and gender effects on pharmacokinetics of rasagiline by enrolling adequate numbers of male and female subjects in different age groups. To exclude the effects of confounding factors, demographic data for the subjects should be carefully collected and recorded.

   Protocol Submission Date: September 17, 2006

   Study Start Date: November 30, 2006

   Final Report Submission Date: October 31, 2007

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call CDR Teresa Wheelous, Sr. Regulatory Management Officer, at (301) 796-1161.

Sincerely,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple
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